BS

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,408	07/11/2003	Paz Einat	67722-A/JPW/FHB	8202

7590 04/19/2005

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,408	EINAT ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3 and 5 drawn to a method for treatment of an apoptosis-related disease comprising administering an antibody against a WWP1 polypeptide, classifiable in class 424, subclass 130.1.

II. Claims 4 and 5 drawn to a method for treatment of an apoptosis-related disease comprising administering an antisense against a WWP1 polypeptide, classifiable in class 536, subclass 24.5.

III. Claims 7 and 9, drawn to a method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antibody against a human WWP1 polypeptide with a chemotherapeutic agent, classifiable in class 424, subclass 130.1.

IV. Claims 8 and 9, drawn to a method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antisense fragment targeted to human WWP1 with a chemotherapeutic agent, classifiable in class 514, subclass 44.

V. Claims 10-11, drawn to an antisense oligonucleotide capable of inhibiting the expression of WWP1 polypeptide, classifiable in class 536, subclass 24.5.

VI. Claims 12, 14 and 16, drawn to a process for determining the WWP1 polypeptide levels in cells of subjects, classifiable in class 424, subclass 130.1.

VII. Claims 13, 15 and 17, drawn to a process for determining levels of polynucleotide encoding WWP1 in a subject, classifiable in class 435, subclass 6.

VIII. Claim 18-22, drawn to a process for obtaining a compound which modulates or promotes apoptosis in a cell, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I, II, III and IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, each method is unrelated because each has a different function and a different effect for the reasons listed below.

The method for treatment of an apoptosis-related disease comprising administering antibody against a WWP1 polypeptide (group I), the method for treatment of an apoptosis-related disease comprising administering an antisense against a WWP1 polypeptide (group II), the method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antibody against a human WWP1 polypeptide with a chemotherapeutic agent (group III) and the method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antisense against a human WWP1 polypeptide with a chemotherapeutic agent (group IV) are all unrelated as they comprise distinct

steps and utilize different products which demonstrates that each method has a different mode of operation.

Furthermore, the method for treatment of an apoptosis-related disease comprising administering antibody against a WWP1 polypeptide, as present in group I, require considerations of what antibody would bind to a WWP1 polypeptide to provide inhibition of the polypeptide. The above method is not useful in the method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antisense compound against a human WWP1 polypeptide with a chemotherapeutic agent, as present in group II, which involves determining what antisense fragment targeted to a gene expressing WWP1 will potentiate a chemotherapeutic treatment. The above methods are not useful in the method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antibody against a human WWP1 polypeptide with a chemotherapeutic agent, as present in group III, which involves determining what antibody in combination with a chemotherapeutic agent will provide a chemotherapeutic treatment of an apoptosis-related disease. The methods of groups I, II and III are not useful in determining what antisense compound in combination with a chemotherapeutic drug will provide a chemotherapeutic treatment of an apoptosis-related disease when combined together, as present in group IV. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I, III and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, the methods of groups I and III involve determining what antibody or what antibody in combination with a chemotherapeutic drug provide inhibition of the polypeptide, which is not involved in determining the complementarity of a nucleic acid sequence to a gene, as present in group V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different inventions are not useful together because they have materially different modes of operation with different effects. For example, the product antisense oligonucleotide of group V can be used as a probe in detection of a gene sequence, which has a materially different effect than the methods of treatment of an apoptosis-related disease comprising administering an antisense targeted to a gene expressing WWP1 of group V. Furthermore restriction is proper because the subject matter is divergent and non-

coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different inventions are not useful together because they have materially different modes of operation with different effects. For example, the product antisense oligonucleotide of group V can be used as a probe in detection of a gene sequence, which has a materially different effect than the methods of treatment of an apoptosis-related disease comprising administering an antisense targeted to a gene expressing WWP1 of group V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I, II, III, IV and group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, groups I-IV involve determining what antibody, antisense compound, antibody in combination with a chemotherapeutic drug or antisense compound in combination with a chemotherapeutic drug will

inhibit expression of a WWP1 polypeptide and treat an apoptosis-related disease. These methods are not useful in determining the levels of WWP1 polypeptide in a subject, as present in group VI, which involves determining efficient levels of the polypeptide in cells or tissues and determination of what technique would provide detection of the polypeptide. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I, II, III, IV and group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, groups I-IV involve determining what antibody, antisense compound, antibody in combination with a chemotherapeutic drug or antisense compound in combination with a chemotherapeutic drug will inhibit expression of a WWP1 polypeptide and treat an apoptosis-related disease. These methods are not useful in determining the levels of polynucleotide encoding WWP1 in a subject, as present in group VII, which involves considerations of determining a probe complementary to the polynucleotide and determining what technique will allow detection. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I, II, III, IV and group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, groups I-IV involve determining what antibody, antisense compound, antibody in combination with a chemotherapeutic drug or antisense compound in combination with a chemotherapeutic drug will inhibit expression of a WWP1 polypeptide and treat an apoptosis-related disease. These methods are not useful in the process of obtaining a compound which modulates or promotes apoptosis in a cell, as present in group VIII, which involve determining a compound, from a vast array of compounds, will bind to a human WWP1 polypeptide and further modulate or promote apoptosis in a cell. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, group V require involves determining what antisense will target a gene encoding a WWP1 polypeptide, which is not useful in determining the levels of WWP1 polypeptide in a subject, as present in group VI, which involves determining

efficient levels of the polypeptide in cells or tissues and determining what technique will provide detection of the polypeptide. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, group V require involves determining what antisense will target a gene encoding a WWP1 polypeptide, which is not useful in determining the levels of WWP1 polypeptide in a subject, as present in group VII, which involves determining a probe complementary to the polynucleotide and determining what technique will allow detection. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not useful together because they have materially different modes of operation with different effects. For example, group V require involves determining what antisense will target a gene encoding a WWP1 polypeptide, which is not useful in the process of obtaining a compound which modulates or promotes apoptosis in a cell, as present in group VIII,

which involves determining a compound, from a vast array of compounds, will bind to a human WWP1 polypeptide and further modulate or promote apoptosis in a cell. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

The inventions of group VI, VII and VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the processes are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation.

The process for determining the level of WWP1 polypeptide in a subject, as present in group VI, involves determining a method that will allow detection of the polypeptide levels in cells or tissues of a subject. This method is not useful in the process of determining the WWP1 polynucleotide levels in a subject, as present in group VII, which involve determining a probe complementary to the polynucleotide and determining what technique will allow detection. The above methods are not useful in the methodology and materials necessary for modulating or promoting apoptosis in a cell, as present in group VIII, which involve determining a compound, from a vast array of compounds, that will bind to a human WWP1 polypeptide and further modulate or promote apoptosis in a cell. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 1 link(s) inventions I, II, III and IV. Claims 2 and 6 link(s) inventions III and IV The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, 2 and 6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635

SEAN McGARRY
PRIMARY EXAMINER
1635